Remarks

The Office Action dated 14 November 2002 has been received and reviewed. Claims 37-39 having been added, the pending claims are claims 1-39. Reconsideration and withdrawal of the rejections are respectfully requested.

New Claims 37-39

New claims 37-39 are presented to provide additional protection for the present invention.

Support for new claim 37 can be found in, e.g., claim 1 (as filed) and in the specification at, e.g., p. 3, lines 5-8.

Support for new claim 38 can be found in, e.g., claim 1 (as filed) and in the specification at, e.g., p. 11, lines 10-15; p. 15, lines 10-17.

Support for new claim 39 can be found in the application as filed at, e.g., p. 10, lines 15-29.

35 U.S.C. §103 Rejections of Claims 1-22 & 24-36

Claims 1-22, and 24-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over France (French Patent No. 724,174) in view of Tilley (U.S. Patent No. 6,435,009) and Dougherty (U.S. Patent No. 4,914,957).

Applicants disagree with this rejection and respectfully request reconsideration and withdrawal for the following reasons.

The present invention is directed to methods and systems for qualitative respirator fit testing. By definition, qualitative respirator fit testing requires the testing of live subjects who can qualitatively assess a respirator's fit by subjectively detecting a test aerosol. The methods and systems involve the use of an "automated aerosol generator system" to reduce variability in the delivery of test aerosol during the testing. In addition, the systems provide a plurality of test stations at which qualitative tests can be simultaneously performed.

System Claims 21, 22, 24, 25

The rejection of these system claims is based on the assertion that "France substantially discloses the instant application's claimed invention of a qualitative respirator fit test system . . . to include the use of a plurality of test stations (the wooden heads 3) and an automated tainted gas system in fluid communication with each test station" is not supported by the reference itself. As noted above, however, "qualitative" respirator fit tests require the use of live test subjects. France, however, discloses wooden heads – not live test subjects. As a result, the assertion provided to support the rejection of independent system claim 21 and its dependent claims is not supported by the cited reference.

Tilley is cited as disclosing an "automated aerosol generation system." However, like France, Tilley is also directed solely as quantitative respirator fit testing systems. As a result, Tilley does not remedy the deficiencies of France itself – that is, it does not provide any motivation or suggestion to supply a "qualitative" respirator fit testing system having a "plurality of test stations" and "an automated aerosol generator system" as recited in claim 21.

For the above reasons, Applicants submit that the Office Action does not identify and support a proper *prima facie* obviousness rejection with respect to claim 21 and its dependent claims.

With respect to dependent claim 22, Applicants note that it is asserted in the Office Action that "[t]he suggestion/motivation for doing so would have been to process more personnel for mask test fit more quickly." Applicants note, however, that neither France or Tilley (the asserted combination) teach qualitative respirator fit testing systems as recited in claim 22. As a result, there are no "personnel" in the testing systems of either France or Tilley. Because these systems do not require personnel, the assertion presented to support the rejection of claim 2 is not supported by France or Tilley.

Applicants further note that the asserted "suggestion/motivation" is that identified by Applicants as an advantage of the systems of the present invention, thus raising the issue as to whether the improper hindsight is the basis for the rejection of claims 21 & 22.

Applicants also note that the Office Action repeatedly notes that patentability is denied "barring a convincing showing of evidence to the contrary." Applicants respectfully submit, however, that the Office Action fails to set forth a proper *prima* facie case of obviousness with respect to system claims 21, 22, 24, and 25. As such, Applicants submit that a request for any such evidence is premature.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this obviousness rejection of system claims 21, 22, 24, & 25.

Method Claims 1-20

The rejection of method claims 1-20 is based on the conclusory assertion that "one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above." No reasoning for that assertion is offered and no support for the assertion is identified in the cited references. As a result, the rejection does not meet the requirements for a *prima facie* obviousness rejection. For that reason alone, Applicants respectfully request withdrawal of the rejection and identification of some suggestion or motivation, supported by the references, be provided to allow Applicants an opportunity to address the basis for any such rejection.

With respect to independent claim 1, for example, Applicants note that the primary references (France and Tilley) disclose only quantitative respirator fit testing methods – not qualitative respirator fit testing as recited in claim 1. No suggestion or motivation is identified as to how or why one of ordinary skill in the art would modify the methods disclosed in the cited references to reach the method recited in independent claim 1 and its dependent claims 2-20.

With respect to claims 2-3 and 7, the same arguments presented above with respect to claim 1 apply. In addition, Applicants note that the cited reference (France) discloses wooden headed test devices and the rejection does not address how such test subjects could be "prompted" as asserted in the Office Action.

With respect to claim 8, Applicants note that the assertion "the suggested device is fully capable of delivering different amounts of aerosol to different test stations/subjects" is not supported by any reasoning or any citation to the references identified in support of this rejection. As such, this rejection does not meet the requirements for a proper *prima facie* case of obviousness.

With respect to claims 9 and 19, Applicants submit that none of the cited references discloses or suggests storing, in a database, test feedback (claim 9) or sensitivity feedback (claim 19) from a test subject undergoing a qualitative respirator fit test. A proper *prima facie* case of obviousness requires that some reasoning and/or suggestion/motivation be identified in support of this rejection.

With respect to claims 10 & 20, Applicants submit that none of the cited references discloses or suggests storing, in a database, information regarding the test aerosol delivery (claim 10) or information regarding the sensitivity aerosol delivery (claim 20) from a test subject undergoing a qualitative respirator fit test. A proper *prima facie* case of obviousness requires that some reasoning and/or suggestion/motivation be identified in support of this rejection.

With respect to claim 11, Applicants submit that because the "suggested device" does not include test subjects in a qualitative respirator fit test, no such monitoring can be performed as asserted.

With respect to claim 12, Applicants note that monitoring screens are not "images" within even the broadest reasonable interpretation of that term as used in connection with the present invention. Furthermore, in the absence of a method involving test subjects in a qualitative respirator fit testing method as recited in claim 1, no such images can be captured.

With respect to claims 13 & 14, Applicants note that Dougherty discloses only a single test station, not a plurality of test stations in the system being used to conduct the respirator fit tests. Furthermore, no suggestion or motivation is identified in the Office Action to support modification of the methods of Dougherty to reach the claimed invention as would be required for a proper *prima facie* case of obviousness.

With respect to claim 18, Applicants note that the assertion "the suggested device is fully capable of selectively shutting off testing of an individual test subject" is not supported by any reasoning or any citation to the references identified in support of this rejection. As such, it does not meet the requirements for a proper *prima facie* case of obviousness.

For the above reasons, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection of method claims 1-20.

Method Claims 26-36

The rejection of method claims 26-36 is based on the conclusory assertion that "the suggested device is fully capable of remote automated test fitting." No reasoning for that assertion is offered and no support for the assertion is identified in the cited references. As a result, the rejection does not meet the requirements for a *prima facie* obviousness rejection. For that reason alone, Applicants respectfully request withdrawal of the rejection and identification of some suggestion or motivation, supported by the references, be provided to allow Applicants an opportunity to address the basis for any such rejection.

With respect to claim 26, Applicants note that the primary references (France and Tilley) disclose only respirator fit testing methods performed at a single site, i.e., the operators and the testing equipment at the same location. No suggestion or motivation is identified as to how or why one of ordinary skill in the art would modify the methods disclosed in the cited references to reach the methods of remote testing recited in independent claim 26 and its dependent claims 27-36.

With respect to claim 28, Applicants submit that none of the cited references discloses or suggests storing, in a database, test feedback from a test subject undergoing a remotely operated respirator fit test. A proper *prima facie* case of obviousness requires that some reasoning and/or suggestion/motivation be identified in support of this rejection.

With respect to claim 29, Applicants submit that none of the cited references discloses or suggests storing, in a database, information regarding the test aerosol delivery from a test subject

undergoing a remotely operated respirator fit test. A proper *prima facie* case of obviousness requires that some reasoning and/or suggestion/motivation be identified in support of this rejection.

With respect to claim 30, Applicants submit that because the "suggested device" does not include test subjects in a remotely operated respirator fit test, no such monitoring can be performed as asserted.

With respect to claim 31, Applicants note that monitoring screens are not "images" within even the broadest reasonable interpretation of that term as used in connection with the present invention. Furthermore, in the absence of a method involving test subjects in a remotely operated respirator fit testing method as recited in claim 26, no such images can be captured.

With respect to claims 35 & 36, Applicants note that the assertion "the suggested device is fully capable of being provided at a remote location in multiples for simultaneous operation" is not supported by any reasoning or any citation to the references identified in support of this rejection. As such, this rejection does not meet the requirements for a proper *prima facie* case of obviousness.

For the above reasons, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection of method claims 26-36.

35 U.S.C. §103 Rejection of Claim 23

Claim 23 was rejected under 35 U.S.C. §103(a) as being unpatentable over France in view of Tilley (U.S. Patent No. 6,435,009) and Dougherty (U.S. Patent No. 4,914,957), and further in view of Loedding et al. (U.S. Patent No. 5,156,776).

Applicants note that system claim 23 depends from dependent claim 22 which, in turn, depends from system claim 21. As noted above, Applicants disagree with the obviousness rejection of claims 21 & 22. Loedding et al. and the reasoning provided in support of the rejection of claim 23 do not remedy any of the deficiencies of the rejections of claims 21 & 22,

As a result, Applicants respectfully submit that claim 23, as presented, is patentable over the asserted combination of France, Tilley, Dougherty and Loedding et al.

For the above reasons, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection of system claim 23.

Summary

It is respectfully submitted that the pending claims 1-39 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

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CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on this 14th day of May, 2003, at 1:52 p.m. (Central Time).

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APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS INCLUDING NOTATIONS TO INDICATE CHANGES MADE

Serial No.: 09/698,412

Docket No.: 56108US002 (formerly 56108USA1A002)

Any amendments to the following claims are indicated by underlining what has been added and bracketing what has been deleted. Additionally, all amendments and new claims have been marked in boldface type

In the Claims

For convenience, all pending claims are shown below.

1. A method of qualitative respirator fit testing, the method comprising:

providing an automated qualitative respirator fit testing system that comprises a plurality of test stations and an automated aerosol generator system in fluid communication with each of the test stations;

locating at least one test subject at one test station of the plurality of test stations; and

conducting a qualitative fit test on each test subject located at one of the test stations, wherein the qualitative fit test conducted at each of the test stations comprises:

delivering a test aerosol to the test station using the automated aerosol generator system after locating a respirator on the test subject, wherein the test subject is exposed to the test aerosol; and

receiving test feedback from the test subject at the test station after exposure to the test aerosol.

2. The method of claim 1, further comprising locating two or more test subjects at the plurality of test stations and conducting a qualitative fit test on each of the two or more test subjects simultaneously.

3. The method of claim 2, wherein delivering the test aerosol further comprises simultaneous delivery of the test aerosol to the two or more test subjects

4. The method of claim 1, wherein the automated aerosol generator system comprises a set of independent aerosol generators, with at least one of the independent aerosol generators in fluid communication with each of the test stations.

5. The method of claim 1, wherein the aerosol generator system comprises at least one aerosol generator in fluid communication with at least two of the plurality of test stations.

6. The method of claim 1, wherein providing the test aerosol further comprises delivering a selected amount of the test aerosol to each of the test subjects at predetermined intervals using the aerosol generator system.

7. The method of claim 6, further comprising delivering the selected amount of the test aerosol to each of the test subjects simultaneously.

8. The method of claim 6, further comprising delivering different selected amounts of the test aerosol to at least two of the test stations.

9. The method of claim 1, further comprising storing the test feedback in a database.

10. The method of claim 1, further comprising storing information regarding the test aerosol delivery to each of the test subjects in a database.

11. The method of claim 1, further comprising monitoring each of the test stations during exposure of the test subjects to the test aerosol.

12. The method of claim 1, further comprising:

monitoring each of the test stations during exposure of the test subject to the test aerosol to

each of the test stations;

capturing at least one image during the monitoring;

storing the at least one image in a database.

13. The method of claim 1, further comprising prompting the test subjects at each of the test stations to perform specified activities during exposure of the test subject to the test aerosol.

14. The method of claim 13, further comprising simultaneous prompting of at least two test subjects to perform the specified activities.

15. The method of claim 13, further comprising receiving activity feedback from each of the test subjects indicating completion of the specified activities.

16. The method of claim 1, wherein the qualitative fit test performed at each of the test stations further comprises:

delivering sensitivity aerosol to the test station using the automated aerosol generator system, wherein the test subject is exposed to the sensitivity aerosol; and

receiving sensitivity feedback from the test subject at the test station after exposure to the sensitivity aerosol.

17. The method of claim 16, further comprising simultaneous delivery of an initial selected amount of the sensitivity aerosol to each of at least two test subjects.

18. The method of claim 16, further comprising preventing delivery of the sensitivity aerosol to at least one test subject after receiving sensitivity feedback from the test subject indicating detection of the sensitivity aerosol by the test subject after delivering the initial selected amount of the sensitivity aerosol.

19. The method of claim 16, further comprising storing the sensitivity feedback in a database.

20. The method of claim 16, further comprising storing information regarding the sensitivity aerosol delivery to each of the test subjects in the database.

21. A qualitative respirator fit testing system comprising:

a plurality of test stations; and

an automated aerosol generator system in fluid communication with each of the test stations.

22. The system of claim 21, wherein the automated aerosol generator system comprises a set of independent aerosol generators, wherein at least one of the independent aerosol generators is in fluid communication with each of the test stations.

23. The system of claim 22, wherein each of the aerosol generators comprises a nebulizer.

24. The system of claim 21, wherein the automated aerosol generator system comprises at least one aerosol generator in fluid communication with at least two of the plurality of test stations.

25. The system of claim 21, wherein each of the test stations comprises a respirator fit testing hood.

26. A method of remote automated respirator fit testing comprising:

providing an automated respirator fit testing system at a first location, wherein the automated respirator fit testing system comprises at least one test station and an automated aerosol generator system in fluid communication with each of the at least one test stations;

locating at least one test subject wearing a respirator at the test station of the respirator fit

testing system at the first location; and

operating the automated respirator fit testing system from a remote location to perform a respirator fit test on the at least one test subject by delivering a test aerosol to the at least one test station using the automated aerosol generator system, wherein the at least one test subject is exposed to the test aerosol.

27. The method of claim 26, wherein operating the respirator fit testing system comprises receiving test feedback at the remote location from the test subject at the first location after exposure to the test aerosol.

28. The method of claim 27, further comprising storing the test feedback in a database.

29. The method of claim 26, further comprising storing information regarding the test aerosol delivery in a database.

30. The method of claim 26, further comprising monitoring the at least one test station while performing the respirator fit test.

31. The method of claim 26, further comprising:
monitoring the at least one test station while performing the respirator fit test;
capturing at least one image during the monitoring;
storing the at least one image in a database.

32. The method of claim 26, further comprising prompting the at least one test subject to perform specified activities while performing the respirator fit test.

33. The method of claim 26, further comprising receiving activity feedback from the at least one

test subject indicating completion of the specified activities while performing the respirator fit test.

34. The method of claim 26, further comprising simultaneous prompting of at least two test subjects to perform the specified activities.

35. The method of claim 26, further comprising:

providing a second automated respirator fit testing system at a second location remote from the first location, wherein the second automated respirator fit testing system comprises at least one test station and an automated aerosol generator system in fluid communication with each of the at least one test stations;

locating at least one test subject wearing a respirator at the test station of the second automated respirator fit testing system at the second location; and

operating the first and second automated respirator fit testing systems from the remote location to perform a respirator fit test on the at least one test subject located at each of the first and second automated respirator fit testing systems, wherein each respirator fit test comprises delivering a test aerosol to the at least one test station using the automated aerosol generator system, wherein the at least one test subject is exposed to the test aerosol.

36. The method of claim 35, further comprising conducting respirator fit tests using the first and second automated respirator fit testing systems at the same time.

37. (NEW) A method of qualitative respirator fit testing, the method comprising:

providing an automated qualitative respirator fit testing system that comprises a plurality of test stations and an automated aerosol generator system in fluid communication with each of the test stations;

locating at least one test subject at one test station of the plurality of test stations; and

conducting a qualitative fit test on each test subject located at one of the test stations,

wherein the qualitative fit test conducted at each of the test stations comprises:

delivering a repeatable, selected amount of test aerosol to the test station using the automated aerosol generator system after locating a respirator on the test subject, wherein the test subject is exposed to the test aerosol; and

receiving test feedback from the test subject at the test station after exposure to the test aerosol.

38. (NEW) A method of qualitative respirator fit testing, the method comprising:

providing an automated qualitative respirator fit testing system that comprises a plurality of test stations and an automated aerosol generator system in fluid communication with each of the test stations;

locating at least one test subject at one test station of the plurality of test stations; and

conducting a qualitative fit test on each test subject located at one of the test stations, wherein the qualitative fit test conducted at each of the test stations comprises:

delivering different selected amounts of test aerosol to at least two of the test stations using the automated aerosol generator system after locating a respirator on test subjects at the at least two of the test stations, wherein the test subjects are exposed to the different selected amounts of test aerosol at the same time; and

receiving test feedback from the test subject at the test station after exposure to the test aerosol.

39. (NEW) The method of claim 1, comprising:

capturing at least one image of at least one test subject at one of the test stations during exposure of the test subject to the test aerosol; and

storing the at least one image in a database.